

REMARKS

Reconsideration of this application is respectfully requested in view of the amendments above and following remarks. Claims 28 to 37 were pending in the present application. Claims 28 to 37 were rejected. Claims 30 and 35 have been canceled. Claims 28, 33 and 36 have been amended. Presently, Claims 28, 29, and 31 to 34, and 37 remain under consideration.

Claim 28 has been amended to incorporate the limitation of Claim 30 to administration by transdermal patch, and to change the term "comprising" to "consisting essentially of" and does not add new matter to the present application. Similarly, Claim 33 has been amended to incorporate the limitation of Claim 35 to administration via transdermal patch, and to change the term "comprising" to "consisting essentially of." Claim 36 has been amended to change the open-ended term "comprising" to "consisting essentially of. . . as the active ingredient." These amendments do not add new matter to the present application.

*Claim Rejections - 35 USC §102*

Claims 28-29 and 31-34 were rejected under 35 USC §102(b) as being anticipated by Rasmusson et al. (EP 0 285 382 A2). In maintaining the rejection, the Examiner stated:

... in response to the argument regarding transdermal application, the term "transdermal" includes any application that it is applied through the unbroken skin (refers to medications [sic] applied directly to the skin (creams, ointments, patch, etc.), see dictionary, World net 1.7 or Webster (copies are enclosed in PTO-892). Topical compositions (i.e. cream, lotion, ointment) taught by the Rasmusson encompass the critical element required by the instant claims (i.e. transdermal application). Thus, Claims 28-29 and 31-34 are anticipated by the Rasmusson reference and the rejection is maintained.

To facilitate prosecution of the present application to allowance, Applicants have amended base Claims 28 and 33 to incorporate the limitations of Claims 30 and 35, respectively, to administration by transdermal skin patch. Rasmusson does not

teach or even suggest the administration of the 5alpha-reductase inhibitor via transdermal skin patch.

In view of the amendments and remarks above, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 28, 29 and 31 to 34.

Claim Rejections - 35 USC §103

Claims 30 and 35-37 were rejected under 35 USC §103(a) as being unpatentable over Rasmusson et al. (EP 0 285 382 A2) in view of Goldman (US 5,407,944). As amended, Claims 28, 29, 31 to 34, 36 and 37 incorporate some of the limitations of Claims 30 and 35. These claims will also be addressed in view of this rejection. In maintaining the rejection, the Examiner stated:

...Applicant argues that the skin patch containing 5-alpha reductase inhibitor is not specifically taught by Goldman (US 5407944). However, this examiner would not agree on applicant's argument because the patented Claims 17 and 19 which are directed to the combination of vasodilator and 5-alpha reductase inhibitor in topical preparation that could be formulated in skin patch in light of the patented disclosure (Column 6, lines 10-20). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention made to modify Rasmusson's teaching with Goldman's to make skin patch composition to increase the selection option and the improve the quality of the therapy by enhancing the compliance wherein the extended formulation would benefit the patient and fit the patient's need.

Applicants respectfully traverse this rejection of Claims 30 and 35 to 37, presently Claims 28, 29, 31 to 34, 36 and 37, over Rasmusson in view of Goldman. As amended, independent, base Claims 28, 33, and 36 currently "consist essentially of" (administration of) the 5 $\alpha$ -reductase inhibitor compound. As Applicants previously noted, the Goldman patent does not suggest transdermal administration of a 5alpha reductase inhibitor including finasteride. Neither does Goldman suggest a transdermal skin patch comprising a therapeutically effective amount of a 5alpha-reductase type 2 inhibitor including finasteride. Goldman does describe several formulations in the patent; namely:

- (1) Minoxidil as a topical solution (col. 3, lines 39-52);

- (2) Minoxidil in tablet form (col. 3, lines 53-62);
- (3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);
- (4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
- (5) Nifedipine as a capsule (col. 4, lines 19-38);
- (6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
- (7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5, line 28);
- (8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
- (9) Finasteride as a tablet (col. 5, lines 43-62).

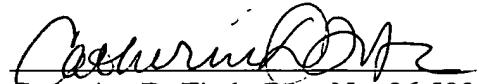
Of the nine formulations listed above from the Goldman patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the Goldman patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The section of Goldman (col. 6, lines 10 and 20, especially line 28) cited by the Examiner does not teach a transdermal skin patch comprising a composition containing 5alpha-reductase 2 inhibitor (e.g., finasteride<sup>¶</sup>), as the Examiner stated. In fact, read in context with the particular formulations Goldman teaches in the patent (cited above), Goldman teaches away from a transdermal skin patch comprising any 5alpha-reductase type 2 inhibitor, including finasteride.

Applicants further submit that Claims 17 and 19 do not teach or suggest a transdermal skin patch of a 5alpha-reductase inhibitor for the treatment of androgenic alopecia to one of ordinary skill in the art at the time of the invention. Claim 19 depends on Claim 17, and *in toto* claims a method for promoting hair growth in a human or other mammal comprising the step of administering a therapeutically effective amount of a vasodilator and a 5-a-reductase inhibitor wherein the step of administration comprises topical administration. However, because Claim 19 employs the open-ended term "comprises" to one of ordinary skill in the art this claim reads on the (more likely) topical administration of the vasodilator coupled with oral administration of the 5alpha-reductase inhibitor.

In view of the amendments and remarks above, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 30 and 35 to 37, presently Claims 28, 29, 31 to 34, 36 and 37, over Rasmusson in view of Goldman.

For the foregoing reasons, Applicants believe that with the present amendments, the instant application is in condition for allowance, or at least in better condition for appeal. If the Examiner has further questions or concerns regarding this application, she is invited to telephone the undersigned attorney at the number below.

Respectfully submitted,

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Date: April 25, 2003

VERSION OF AMENDED CLAIMS  
WITH MARKINGS TO SHOW CHANGES MADE

28. (Amended) A method of treating androgenic alopecia consisting essentially of comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor by a transdermal skin patch.

33. (Amended) A method of treating androgenic alopecia consisting essentially of comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17 $\beta$ -(N-tert-butylcarbamoyl)-4-aza-5 $\alpha$ -androst-1-ene-3-one by a transdermal skin patch.

36. (Amended) A transdermal skin patch consisting essentially of comprising a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.